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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,009	03/24/2001	Mark B. Lyles	068986.0103	5744

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EXAMINER	
EPPERSON, JON D	
ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/817,009	LYLES, MARK B.	
	Examiner	Art Unit	
	Jon D Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-10,13 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-10,13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. The Response filed May 19, 2004 is acknowledged.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Claims

3. Claims 1-36 were pending. Applicants amended claims 1, 3, 7-9 and canceled claims 2, 11, 12 and 15-36. Therefore, claims 1, 3-10, 13 and 14 are currently pending and examined on the merits.

Withdrawn Objections/Rejections

4. All outstanding objections and/or rejections are withdrawn in view of Applicants' arguments and/or amendments.

New Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 3-10, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glazer et al. (Glazer, M.; Frank, C.; Vinci, R. P.; Mcgali, G.; Fidanza, J.; Beecher, J. "High surface area substrates for DNA arrays" *Materials Research Society Symposium Proceedings* **1999**, *576*, 371-376) and Yasukawa, et al. (U.S. patent No. 5,629,186).

For ***claim 1***, Glazer et al. (see entire document) disclose high surface area substrates for DNA arrays (see Glazer et al., abstract), which reads on claim 1. For example, Glazer et al. disclose two-dimensional arrays of biomolecules that contain at least 100 different molecules on a porous substrate at predefined regions (see Glazer et al., pages 371-2, Introduction; see also figure 1-2).

For **claims 10, 13 and 14**, Glazer et al. disclose both oligonucleotides and DNA (e.g., see Glazer et al., pages 371-2, Introduction). Although Glazer et al. does not explicitly disclose RNA, the reference does teach the genus oligonucleotides which only contains two possible species i.e., DNA or RNA and, as a result, the species RNA would be rendered obvious (e.g., see In *In re Schauman*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978), wherein claims to a specific compound were anticipated because the prior art taught a generic formula embracing a limited number of compounds closely related to each other in structure and the properties possessed by the compound class of the prior art was that disclosed for the claimed compound). Here, the genus contains only RNA and DNA and they are closely related in structure because they only differ by one –OH group.

The prior art teachings of Glazer et al. differ from the claimed invention as follows:

For ***claim 1***, Glazer et al. are deficient in that they do not teach a fused fiber porous material that is manufactured from alumina fibers, silica fibers, and a fusion source. Glazer et al. only recite porous materials that are 67.4% SiO_2, 25.7% B_2O_3 and 6.9% Na_2O (see Glazer et al., page 372, Experiment, Sodium borosilicate glass; see also page 372, paragraphs 2-4).

For **claims 3 and 4**, Glazer et al. are deficient in that it does not specifically recite that the porous material can comprise fused fibers of alumina, silica and a fusion source like boron. Furthermore, Glazer et al. also does not recite that the porous material can be made from a compositions comprising about 1% to about 50% by weight alumina, about 50% to about 98% by weight silica, and about 1% to about 5% by weigh boron. Glazer et al. only recites that materials that are 67.4% SiO_2, 25.7% B_2O_3 and 6.9% Na_2O (see Glazer et al., page 372, Experiment, Sodium borosilicate glass; see also page 372, paragraphs 2-4).

For **claim 5**, Glazer et al. are deficient in that it does not specifically recite a pore radius e.g., greater than about 10 microns.

For **claim 6**, Glazer et al. are deficient in that it does not specifically recite the limitation that the porous material must be at least about 6 pounds per cubic foot.

For **claims 7-9**, Glazer et al. are deficient in that it does not specifically recite the that the percentage of exposed surface is at least about 50%, 75% or 95% silicon dioxide.

However, Yasukawa, et al. teach the following limitations that are deficient in Glazer et al.:

For ***claim 1***, Yasukawa et al. teach fused fibrous ceramic materials that are prepared from amorphous silica and/or alumina fibers with 2 to 12 % boron nitride (e.g., see Yasukawa, et al., abstract).

For ***claims 3 and 4***, Yasukawa et al. teach porous materials with silica, alumina and boron wherein the composition by weight is about 1% to about 50% by weight alumina, about 50% to about 98% by weight silica, and about 1% to about 5% by weight boron (e.g., see Yasukawa et al., column 3, lines 66-67, "80 percent of fiber weight of silica fibers and 20 percent by fiber weight of alumina fibers"; see also column 2, lines 4-6, "boron nitride particles, in an amount between about 2-12 percent by weight of the total fiber weight").

For ***claim 5***, Yasukawa et al. disclose the "silica fibers have ... fiber diameters between about 5 to 20 μm" (e.g., see column 1, lines 34-35 wherein 20 μm >> 10 μm).

For ***claim 6***, Yasukawa et al. disclose that the matrix may have a density of 3.5 to 12 pounds per cubic foot which is "at least about" 6 pounds per cubic foot (e.g., see claim 8; see also column 1, line 29)

For ***claims 7-9***, Yasukawa, et al. does not disclose the % silicon dioxide at the exposed surface, but the material is produced using the same alumina/silica fibers and the same boron source in the same proportions and, as a result, would be expected to possess the same % silicon dioxide at the exposed surface as that claimed by Applicants. "When the PTO shows a sound basis for believing that the products of the applicant and the prior

art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See *In re Best,* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

It would have been obvious to one skilled in the art at the time the invention was made to use the porous materials disclosed by Yasukawa et al. with the invention as disclosed by Glazer et al. because Glazer explicitly state that porous materials can be used to increase the number of immobilized probe molecules in DNA arrays (e.g., see Glazer et al, page 372, paragraph 2, "Porous surface layers are a potential routes to increasing the signal from DNA arrays, as they increase the total surface area on which probes can be attached, and hence the capacity for bound target molecules"), which would encompass the porous materials disclosed by Yasukawa. In addition, a person of skill in the art would have been motivated to use the porous material disclosed by Yasukawa et al. because Glazer et al. states, "Inorganic surfaces have the advantage that they are similar to the original glass substrate, so that array fabrication protocols can be used", which would encompass the "inorganic" silica/alumina fibers disclosed by Yasukawa et al. Yasukawa et al. also state that their matrix has "relatively larger pores" (e.g., see column 1, line 36) that liquid samples could more easily penetrate. In addition, a person of skill in the art would have reasonable expected to be successful because Yasukawa et al. state that the "silica fibers may be derivatized with molecules effective to bind ligand molecules passed through the matrix" (e.g., see column 1, lines 55-56; see

also figures 13A-B; see also column 1, lines 49-50, "the matrix may be coated with a biocompatible material at its outer surface"), which would be required for the fabrication of a biological array.

6. Claims 1, 3-10, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al. (U.S. Pat. No. 5,959,098) (Filing Date is **April 17, 1996**) and Yasukawa, et al. (U.S. patent No. 5,629,186).

For ***claim 1***, Goldberg et al (see entire document) disclose a substrate for the attachment of an array of greater than 100 different biomolecules bound to different predetermined regions of the surface of the porous material (see Goldberg et al., column 6, section IV), which anticipates claim 1. For example, Goldberg et al discloses a two-dimensional array comprising molecules bound to the material surface (see Goldberg et al, column 6 lines 50-57, see also column 6 last paragraph). Goldberg et al also discloses that said material surface may be porous (see Goldberg et al, column 6, lines 39-49, "Silica aerogels may also be used as substrates ... Porosity may be adjusted by altering reaction conditions by methods known in the art"). Goldberg also discloses that at least 100 different molecules may be bound to the surface of the porous material in different predetermined regions (see Goldberg et al, column 2, lines 2-4, "Each polymer array includes a plurality of different polymer sequences coupled to the surface of the substrate wafer in a different known location") (see also columns 9-14, section V; see especially column 10, last paragraph, "Using the above described methods, arrays may be prepared having all polymer sequences of a given length ... For an array of 8mer or 10mer

oligonucleotides, such arrays could have upwards of about 65,536 and 1,048,576 different oligonucleotides respectively").

For ***claims 10, 13 and 14***, Goldberg et al discloses an array of oligonucleotides (see Goldberg et al, columns 9-14, section V; see especially column 10, last paragraph, "Using the above described methods, arrays may be prepared having all polymer sequences of a given length ... For an array of 8mer or 10mer oligonucleotides, such arrays could have upwards of about 65,536 and 1,048,576 different oligonucleotides respectively"), which anticipates claim 10. Furthermore, Goldberg discloses nucleic acids, a broad term, which would encompass both RNA and DNA. Furthermore, the chemistry for the solid-phase synthesis of both RNA and DNA via modification of the silanol groups is well known in the art. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See *In re Best,* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

The prior art teachings of Goldberg et al. differ from the claimed invention as follows:

For ***claim 1***, Goldberg et al. are deficient in that they do not teach a fused fiber porous material that is manufactured from alumina fibers, silica fibers, and a fusion source.

For **claims 3 and 4**, Goldberg et al. is deficient in that it does not specifically recite that the porous material can comprise alumina, silica and boron. Furthermore, Goldberg et al. also does not recite that the porous material can be made from a compositions comprising about 1% to about 50% by weight alumina, about 50% to about 98% by weight silica, and about 1% to about 5% by weigh boron. Goldberg et al. only recites that that "[p]referred substrates generally comprise planar crystalline substrates such as silica based substrates" (see Goldberg et al., column 6, lines 30-31).

For **claim 5**, Goldberg et al. is deficient in that it does not specifically recite a pore radius e.g., greater than about 10 microns. Goldberg et al. is only teach generally that the porosity may be adjusted using known methods in the art (see Goldberg et al., column 6, lines 39-49).

For **claim 6**, Goldberg et al. is deficient in that it does not specificlly recite the limitation that the porous material must be at least about 6 pounds per cubic foot.

For **claims 7-9**, Goldberg et al. is deficient in that it does not specifically recite the that the percentage of exposed surface is at least about 50%, 75% or 95% silicon dioxide.

However, Yasukawa, ET AL. teach the following limitations that are deficient in Goldberg et al.:

For ***claim 1***, Yasukawa et al. teach fused fibrous ceramic materials that are prepared from amorphous silica and/or alumina fibers with 2 to 12 % boron nitride (e.g., see Yasukawa, et al., abstract).

For ***claims 3 and 4***, Yasukawa et al. teach porous materials with silica, alumina and boron wherein the composition by weight is about 1% to about 50% by weight alumina, about 50% to about 98% by weight silica, and about 1% to about 5% by weight boron (e.g., see Yasukawa et al., column 3, lines 66-67, "80 percent of fiber weight of silica fibers and 20 percent by fiber weight of alumina fibers"; see also column 2, lines 4-6, "boron nitride particles, in an amount between about 2-12 percent by weight of the total fiber weight").

For ***claim 5***, Yasukawa et al. disclose the "silica fibers have ... fiber diameters between about 5 to 20 μm" (e.g., see column 1, lines 34-35 wherein 20 μm >> 10 μm).

For ***claim 6***, Yasukawa et al. disclose that the matrix may have a density of 3.5 to 12 pounds per cubic foot which is "at least about" 6 pounds per cubic foot (e.g., see claim 8; see also column 1, line 29)

For ***claims 7-9***, Yasukawa, et al. does not disclose the % silicon dioxide at the exposed surface, but the material is produced using the same alumina/silica fibers and the same boron source in the same proportions and, as a result, would be expected to possess the same % silicon dioxide at the exposed surface as that claimed by Applicants. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See *In re Best,* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

It would have been obvious to one skilled in the art at the time the invention was made to use the porous materials disclosed by Yasukawa et al. with the invention as disclosed by Goldberg et al. because Goldberg et al. explicitly state that "[p]referred substrates generally comprise planar crystalline substrates such as silica based substrates" (see Goldberg et al., column 6, lines 30-31), which would encompass the silica based substrates disclosed by Yasukawa et al. (i.e., the silica/alumina/boron substrates). In addition, a person of skill in the art would have been motivated to use the porous material disclosed by Yasukawa et al. because silica/alumina/boron substrate disclosed by Yasukawa et al. has "relatively larger pores" (e.g., see column 1, line 36) that liquid samples could more easily penetrate. In addition, a person of skill in the art would have reasonable expected to be successful because Yasukawa et al. state that the "silica fibers may be derivatized with molecules effective to bind ligand molecules passed through the matrix" (e.g., see column 1, lines 55-56; see also figures 13A-B; see also column 1, lines 49-50, "the matrix may be coated with a biocompatible material at its outer surface"), which would be required for the fabrication of a biological array.

Conclusion

Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
September 6, 2004

BENNETT CELSA
PRIMARY EXAMINER